SECTION 5
510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4560
Fax: 508-683-5939

Contact: Janis F. Taranto, M.S., RAC
Regulatory Affairs Specialist
Date Prepared: December 31, 2012

DEC 06 2013

2. Proposed Device:

Trade Name: Ultraflex™ Esophageal NG Stent System
Classification Name: Esophageal Prosthesis
Regulation Number: 878.3610
Product Code: ESW
Classification: Class II

3. Predicate Device:

Trade Name: Ultraflex™ Esophageal NG Stent System
Manufacturer and Clearance Number: Boston Scientific Corporation, K091816, K120983
Classification Name: Esophageal Prosthesis
Regulation Number: 878.3610
Product Code: ESW
Classification: Class II

Trade Name: Ultraflex™ Tracheobronchial Stent System
Manufacturer and Clearance Number: Boston Scientific Corporation, K121048
Classification Name: Prosthesis, Tracheal, Expandable
Regulation Number: 878.3720
Product Code: JCT
Classification: Class II

4. Proposed Device Description:

The proposed Ultraflex Esophageal NG Stent System allows for the placement of a self-expanding metallic stent within the esophagus. The systems consist of a flexible delivery catheter preloaded with an expandable stent. The stent is offered either bare or covered and with either a proximal release or distal release delivery system. The stent may be placed fluoroscopically using radiopaque markers as a guide or endoscopically using the visual marker on the delivery catheter. The proposed device incorporates an updated Magnetic Resonance (MR) Conditional statement in the Directions for Use.

5. Indications for Use:
Ultraflex™ Esophageal NG Stent System (non-covered) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only.

Ultraflex™ Esophageal NG Stent System (covered) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only, and occlusion of concurrent esophageal fistula.

6. Technological Characteristics:
The proposed Ultraflex™ Esophageal NG Stent System is identical in design and materials to the predicate Ultraflex™ Esophageal NG Stent System (K091816, K120983) while incorporating an updated MR Conditional statement in the Directions for Use stating compatibility with 1.5 and 3.0 Tesla use. This MR Conditional statement is identical to the statement used in the Ultraflex™ Tracheobronchial Stent System (K121048) DFU.

7. Performance Data:
Magnetic Resonance testing has been performed for the Ultraflex™ Esophageal NG Stent. The Directions for Use meet the requirements for MR Conditional labeling per ASTM standard F 2503-08.

8. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed Ultraflex™ Esophageal NG Stent System with the minor labeling change to update the MR Conditional statement in the DFU, is substantially equivalent to Boston Scientific Corporation's currently marketed Ultraflex™ Esophageal NG Stent System (K091816, K120983) and Ultraflex™ Tracheobronchial Stent System (K121048).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Boston Scientific Corporation
Janis F. Taranto, M.S., RAC
Senior Regulatory Affairs Specialist
100 Boston Scientific Way, M-11
Marlborough, MA 01752

Re: K130004
Trade/Device Name: Ultraflex™ Esophageal NG Stent System
Regulation Number: 21 CFR§ 878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: November 7, 2013
Received: November 8, 2013

Dear Janis F. Taranto,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):	K130004
Device Name:	Ultraflex™ Esophageal NG Stent System
Indications for Use:	Ultraflex™ Esophageal NG Stent System (covered) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only, and occlusion of concurrent esophageal fistula.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2013.12.09 20:05:46 -05'00'

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130004

Device Name: Ultraflex™ Esophageal NG Stent System

Indications for Use: Ultraflex™ Esophageal NG Stent System (non-covered) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2013.12.09 20:06:40 -05'00'